REMARKS

Claims 1-10 were present in the application as originally filed and new claims 11-17 were presented by a preliminary amendment filed with the application. Claims 16 and 17 are cancelled by amendment, and new claim 18 is added.

Telephone Interview

A telephone interview between applicants' undersigned attorney and Examiner Isis Ghali was conducted on February 18, 2004. This use of the Examiner's time, and her cooperation in facilitating prosecution of the present application, are greatly appreciated. During the interview, the teachings of US Patent No. 5,035,894 to Lee and U.S. Patent No. 5,779,632 to Dietz were discussed, along with possible claim amendments to overcome the rejections in the outstanding Office action.

Rejections under 35 U.S.C.§112

Claims 1-17 are rejected under 35 USC §112, first paragraph, as failing to comply with the written description requirement, on the grounds that the term " solution-type adhesive" was not described in the specification as originally filed. As this term is deleted in the amendment to claim 1 above, the rejection is now moot.

Rejections under 35 U.S.C.§102

Claims 1 and 3 are rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 5,035,894, to Lee, *et al*. The rejection is traversed.

The Lee patent relates to adhesive compositions including blends of polyethylene oxide-grafted silicone polymers with resinous copolymers, and transdermal drug delivery devices incorporating these adhesive compositions (Abstract). The reaction scheme described in col. 11, lines 40-60 how to graft acrylate functionality to the siloxane backbone; methyl methacrylate monomer may be grafted to the backbone in a subsequent transesterification step (col. 11, lines 58-60). Claim 1 is now amended to recite a "composition for use in manufacturing a transdermal preparation". This composition includes a non-aqueous solvent, a drug to be delivered through skin and a polymer having an acrylic backbone; the drug is hydrophilic or in a

salt form and the (acrylate) polymer has a polyethylene oxide or polyethylene oxide monomethyl ether side chain. As the Lee patent relates to adhesives composed of polymers having a siloxane backbone with pendant (meth)acrylate functionality, Applicants submit that claim 1 and claim 3, which depends from claim 1 and contains the limitations thereof, are not anticipated by the reference. It is believed that the rejection is hereby overcome.

Claims 1, 2, 16 and 17 are rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 5,779,632 to Dietz, *et al.* The rejection is traversed

Dietz relates to a adhesive composition prepared by photopolymerization of an aqueous microemulsion (Abstract) that may include polyethylene oxide acrylate monomers/oligomers (col. 10, lines 31-43). With the amendment to claim 1 discussed above, the claims are now limited to a non-aqueous *solution* of an acrylate polymer. As Dietz discloses only polymer *emulsions*, applicants submit that Dietz does not anticipate claim 1, or dependent claim 2. Claims 16 and 17 are now cancelled. It is believed that the rejection is overcome.

In addition, it should be noted that one of the advantages of the invention, as described in the specification, is the ability to dissolve a drug that is hydrophilic or in the form of a salt in PEO acrylates in high concentration, without the need for water. This is not disclosed by the reference. This also avoids the disadvantage of using emulsion-type acrylic adhesives in a composition containing these drugs, since formulating a drug in salt form into an emulsion polymer in an amount sufficient to have the desired therapeutic effect can cause breaking of the emulsion, and subsequent agglomeration of the polymer. As a consequence, loading of the drug in the adhesive composition may be limited.

Rejections under 35 U.S.C.§103

Claims 2, and 4-15 are rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 5,035,894 to Lee, *et al.*, in view of U.S. Patent No. 5,865,792 to Ledger, *et al.* Claims 3, 6-11, and 13-15 are rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 5,779,632 to Dietz, *et al.*, in view of U.S. Patent No. 5,865,792 to Ledger, *et al.* The rejections are traversed.

The teachings of the Lee and Dietz patents are set forth above. Ledger relates to an electrotransport device for delivering an ionized drug wherein the drug is contained in a reservoir (claim 1). The matrix of the reservoir may be composed of a hydrophilic polymer, including blends of polyethylene oxide with polyacrylic acid (col. 9, lines 15-35). The device may contain an adhesive applied to the face of the reservoir; composition of the adhesive is unspecified (col. 5, lines 60-67).

As set forth above, neither Lee nor Dietz disclose the invention as claimed. Lee relates to adhesives composed of siloxane polymers, and is silent regarding polymers having an acrylate backbone and a polyethylene oxide side chain. Dietz discloses microemulsions containing polymers of polyethylene oxide acrylates, and makes no mention of non-aqueous solutions of such polymers. Ledger fails to supply the deficiency of either reference, as it merely states that an adhesive may be used, without providing any details how to prepare it. Therefore, Applicants submit that claims 2-4, 6-11 and 13-15 are not obvious over either Lee or Dietz, in view of Ledger. It is believed that the rejection is hereby overcome.

New claim 18, which relates to a method for manufacturing a transdermal preparation, includes a step of combining the same non-aqueous polymer solution as recited in claim 1 with a drug to be delivered through skin. Applicants submit that claim 18 is patentable over the cited references for the same reasons as claim 1.

Respectfully submitted,

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